

**Plaintiffs' Memorandum in Opposition  
to Joint Motion for Summary  
Judgment for Failure to Prove Fault  
Element of Public Nuisance Claims**

**Ex 10 – MCKMDL00407451**



# Prescription Drug Abuse

*The National Perspective*



BUSINESS  
CARE  
CONNECTIVITY

# The Current Landscape: **EPIDEMIC**

The Centers for Disease Control and Prevention (CDC) has declared prescription drug abuse to be an epidemic. □



## Prescription Drug Overdoses - a U.S. Epidemic

□ In 2007, approximately 27,000 unintentional drug overdose deaths occurred in the United States, one death every 19 minutes. Prescription drug abuse is the fastest growing drug problem in the United States. □

CDC Grand Rounds. Morbidity and Mortality Weekly Report January 13, 2012/Vol.61/No.1  
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6101a3.htm>, accessed Jan 15, 2014

# The Current Landscape: **EPIDEMIC**

Every component of the distribution chain has been breached

## A New Painkiller Crackdown Targets Drug Distributors

New York Times, October 18, 2012;  
[http://www.nytimes.com/2012/10/18/business/to-fight-prescription-painkiller-abuse-dea-targets-distributors.html?\\_r=0](http://www.nytimes.com/2012/10/18/business/to-fight-prescription-painkiller-abuse-dea-targets-distributors.html?_r=0), accessed Jan 15, 2014

## 'Candy Man' Doctor Julio Gabriel Diaz Pleads Guilty To Drug Trafficking In Drug Deaths

The Huffington Post January 9, 2014;  
[http://www.huffingtonpost.com/2014/01/09/candy-man-doctor-julio-gabriel-diaz-guilty\\_n\\_4570865.html](http://www.huffingtonpost.com/2014/01/09/candy-man-doctor-julio-gabriel-diaz-guilty_n_4570865.html), accessed Jan 15, 2014

## Heroin and Prescription Stir a Battle Cry in Vermont

ABC News January 15, 2014;  
<http://abcnews.go.com/m/story?id=2153782>  
accessed Jan 15, 2014

## America's fastest-growing drug problem: Prescription drug abuse

CBS News, April 19, 2011; <http://www.cbsnews.com/news/americas-fastest-growing-drug-problem-prescription-drug-abuse/>, accessed Jan 15, 2014

## New Colorado campaign targets teen prescription drug abuse

The Denver Post January 15, 2014;  
<http://www.denverpost.com/2014/01/15/new-colorado-campaign-targets-teen-prescription-drug-abuse/>, accessed Jan 15, 2014

## Doctors Group Backs Tougher Rules Targeting Prescription Drug Abuse

ABC News December 10, 2013;  
<http://abcnews.go.com/blogs/health/2013/12/10/doctors-group-backs-tougher-rules-targeting-prescription-drug-abuse/>, accessed Jan 15, 2014

## Sharp Rise in Women's Deaths From Overdose of Painkillers

NY Times, July 2, 2013; <http://www.nytimes.com/2013/07/03/health/rate-of-painkiller-overdose-deaths-rises-among-women.html>, accessed Jan 15, 2014

## White House launches effort to combat soaring prescription drug abuse

CNN.com April 19, 2011; <http://www.cnn.com/2011/HEALTH/04/19/drug.abuse/>, accessed Jan 15, 2014

# Prescription Drug Abuse is an Epidemic in the U.S.

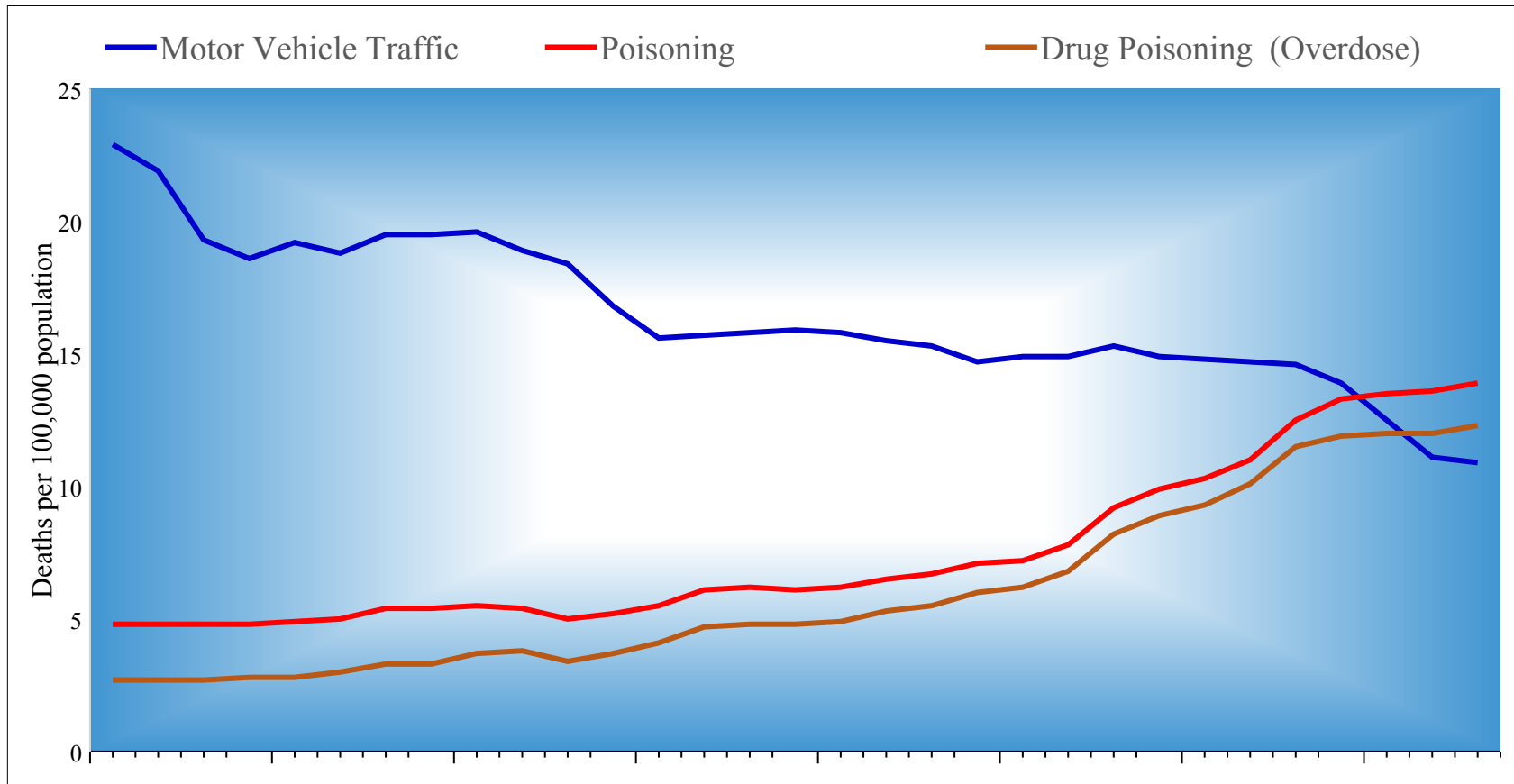
- ☐ Prescription drugs cause more deaths than heroin and cocaine combined\*
- ☐ Prescription drug abuse goes beyond a legitimate medical need
  - ☐ Taken without a prescription
  - ☐ Taken differently than prescribed
  - ☐ Taken for the "high"
- ☐ The US consumes 83% of the world's oxycodone and 99% of the world's hydrocodone, two highly prescribed opioid drugs for pain\*\*

Sources: Centers for Disease Control and Prevention; National Institute on Drug Abuse; International Narcotics Control Board; DEA.

\*Topics in Brief: Prescription Drug Abuse. In *National Institute on Drug Abuse*. <http://www.drugabuse.gov/publications/topics-in-brief/prescription-drug-abuse> (accessed February 2014).

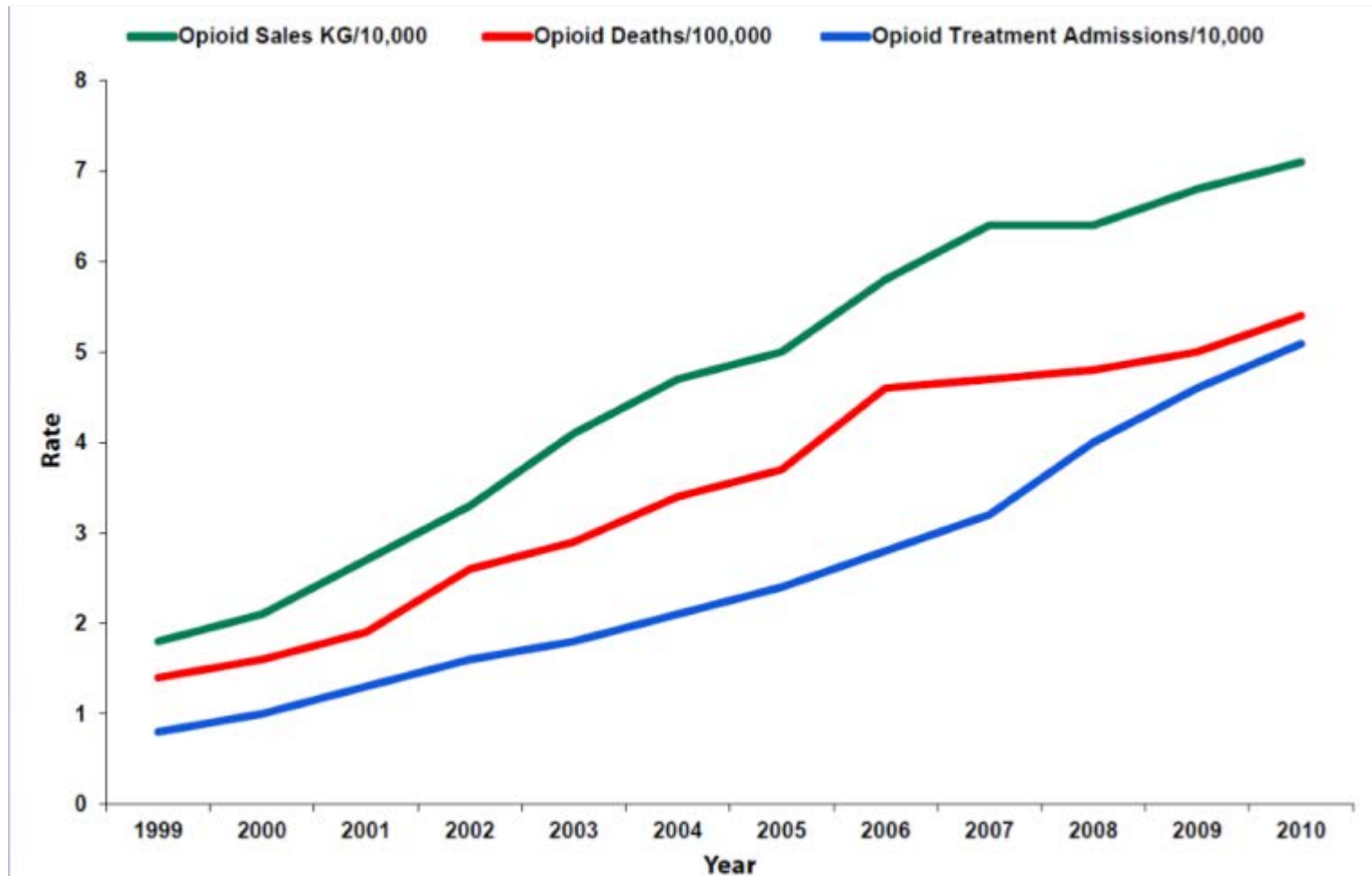
\*\* *International Narcotics Control Board Report 2008*, United Nations Publication 2009, p. 20

# U.S. Death Rate Trends, 1980-2010



Source: Centers for Disease Control and Prevention, National Centers for Health Statistics Data Brief Number 81, December 2011, Updated with 2009 and 2010 mortality data.  
<http://www.cdc.gov/nchs/data/databriefs/db81.htm>, accessed February 2014

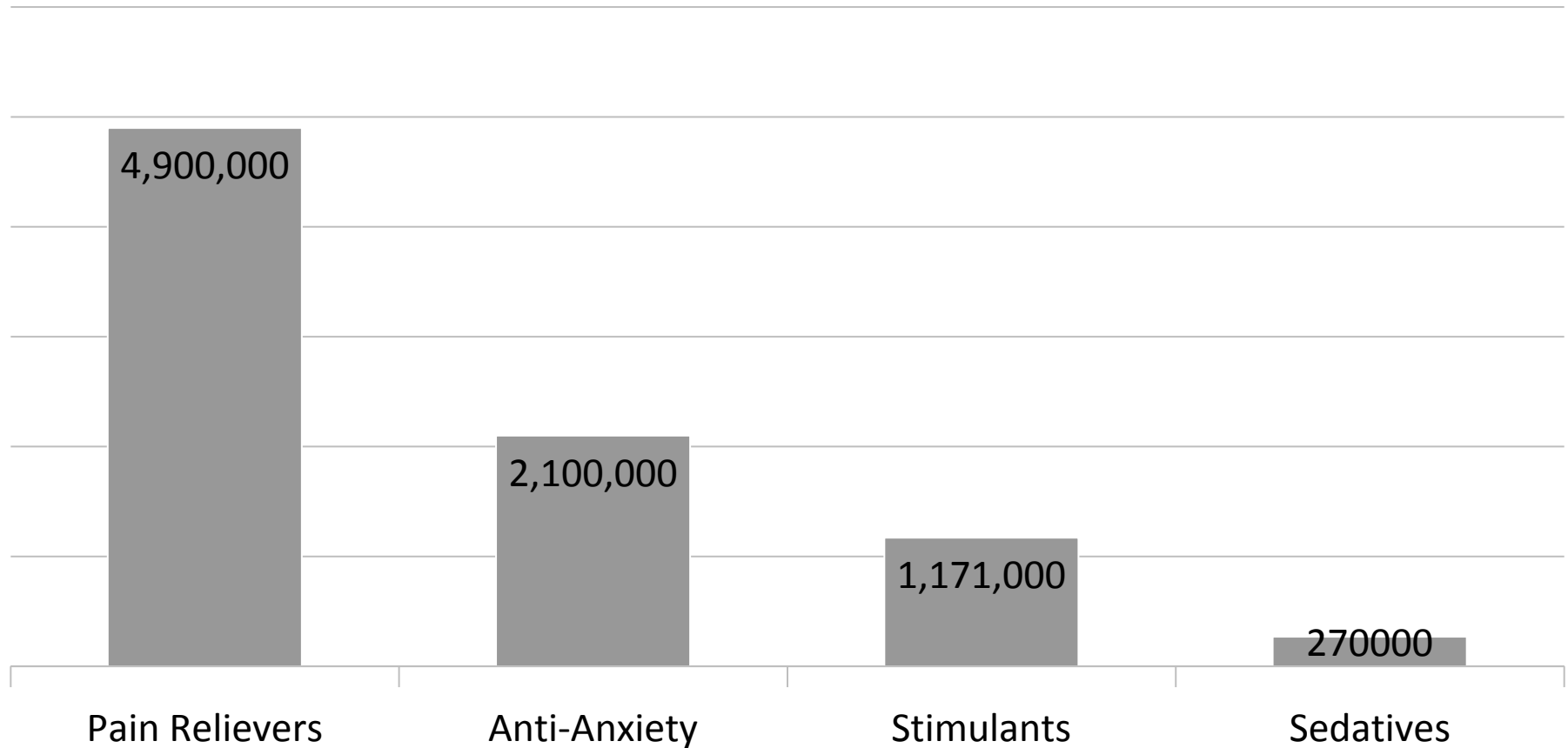
# U.S. Rates of Opioid Overdose Deaths, Sales, and Treatment Admissions, 1999-2010



Source: CDC. *MMWR* 2011. [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm60e1101a1.htm?s\\_cid=mm60e1101a1\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm60e1101a1.htm?s_cid=mm60e1101a1_w). Updated with 2009 mortality and 2010 treatment admission data. Accessed February 2014

# Prescription Drug Abuse □ 2012

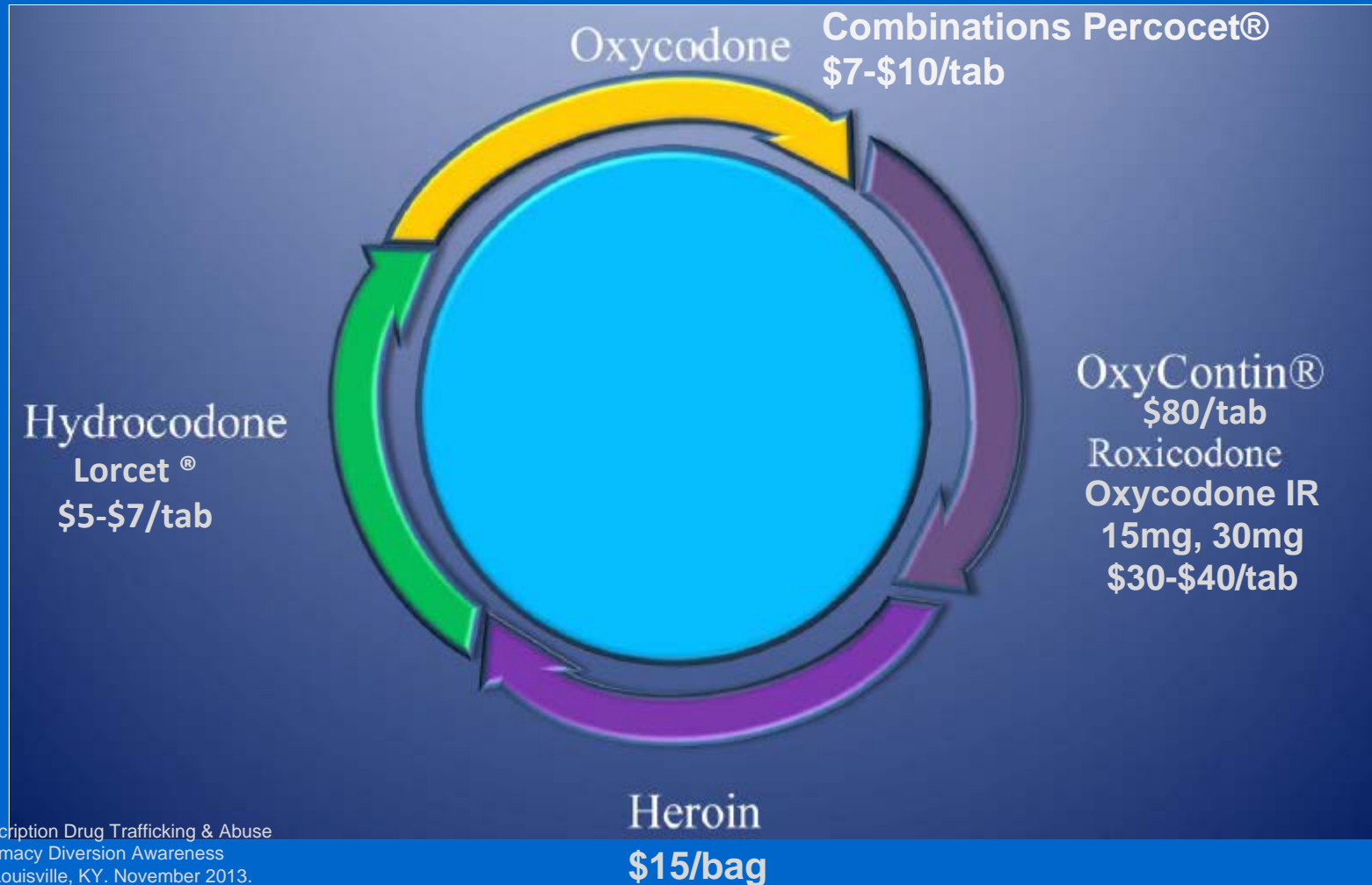
6.8 Million Americans



Source: Substance Abuse and Mental Health Services Administration, Results from the 2012 National Survey on Drug Use and Health, <http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/Index.aspx>, (Accessed February 2014)



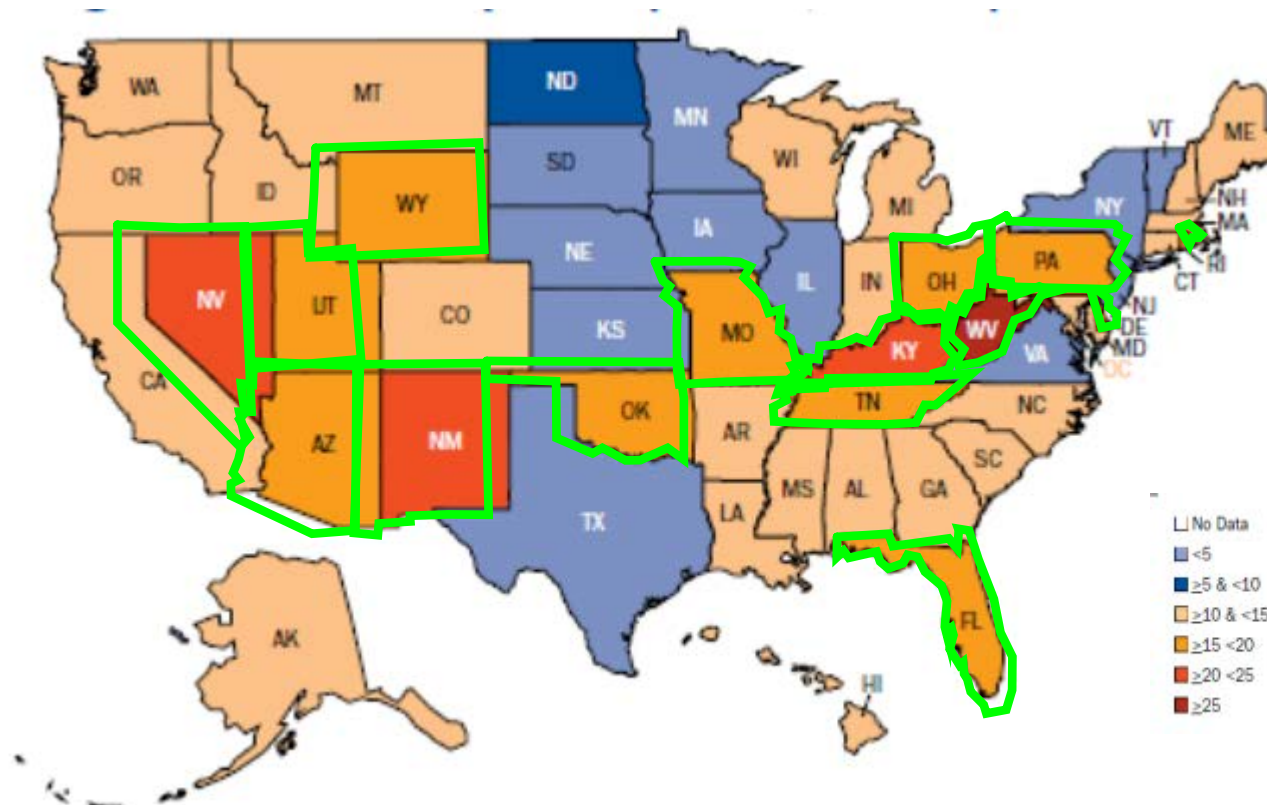
# Circle of Addiction & The Next Generation



Source: Prescription Drug Trafficking & Abuse Trends. Pharmacy Diversion Awareness Conference, Louisville, KY. November 2013.

# Current Drug Abuse Trends

## Overdose Mortality Rates per 100,000 People (2010)\*



\*This includes all drug deaths from prescription drugs, heroin, cocaine etc

Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2010 on CDC WONDER Online Database, released 2012. Data are from the Multiple Cause of Death Files, 1999-2010, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program.  
<http://wonder.cdc.gov/mcd-icd10.html> (accessed February 2014).

### Highest Rates (green)

- |                        |                          |                        |
|------------------------|--------------------------|------------------------|
| 1. West Virginia: 28.9 | 6. Arizona: 17.5         | 11. Florida: 16.4      |
| 2. New Mexico: 23.8    | 7. Missouri: 17          | 12. Ohio: 16.1         |
| 3. Kentucky: 23.6      | 8. Tennessee: 16.9 (tie) | 13. Rhode Island: 15.5 |
| 4. Nevada: 20.7        | 9. Utah: 16.9 (tie)      | 14. Pennsylvania: 15.3 |
| 5. Oklahoma: 19.4      | 10. Delaware: 16.6       | 15. Wyoming: 15        |

# Current Prescription Drug Diversion Trends

## States with Highest Pharmacy Dispensing in 2012\*

Rank	Oxycodone	Hydrocodone	Hydromorphone	Oxymorphone
1	Florida	California	California	North Carolina
2	Pennsylvania	Texas	Florida	California
3	California	Tennessee	New York	Tennessee
4	New York	Michigan	Texas	New York
5	Ohio	Florida	Virginia	Pennsylvania
6	North Carolina	Illinois	Pennsylvania	Florida
7	New Jersey	Ohio	Washington	Ohio
8	Arizona	Indiana	Ohio	Texas
9	Tennessee	Georgia	Michigan	Indiana
10	Massachusetts	Alabama	New Jersey	Virginia

\* Data applies to retail pharmacy dispensing

\* Source: DEA Distributors Conference October 2013



## Case Study: Florida

# Florida Pill Mills

2009 & 2010

Average purchase of  
oxycodone products  
by a pharmacy ?  
63,294 d.u. per year



# State of Florida Legislative Actions\*

## Effective October 1, 2010

- ☐ Pain clinics are banned from advertising that they sell narcotics
- ☐ They can only dispense 72-hour supply of narcotics
- ☐ Prohibits the registration of pain clinics unless they are owned by physicians or licensed by non-physicians as a health care clinic

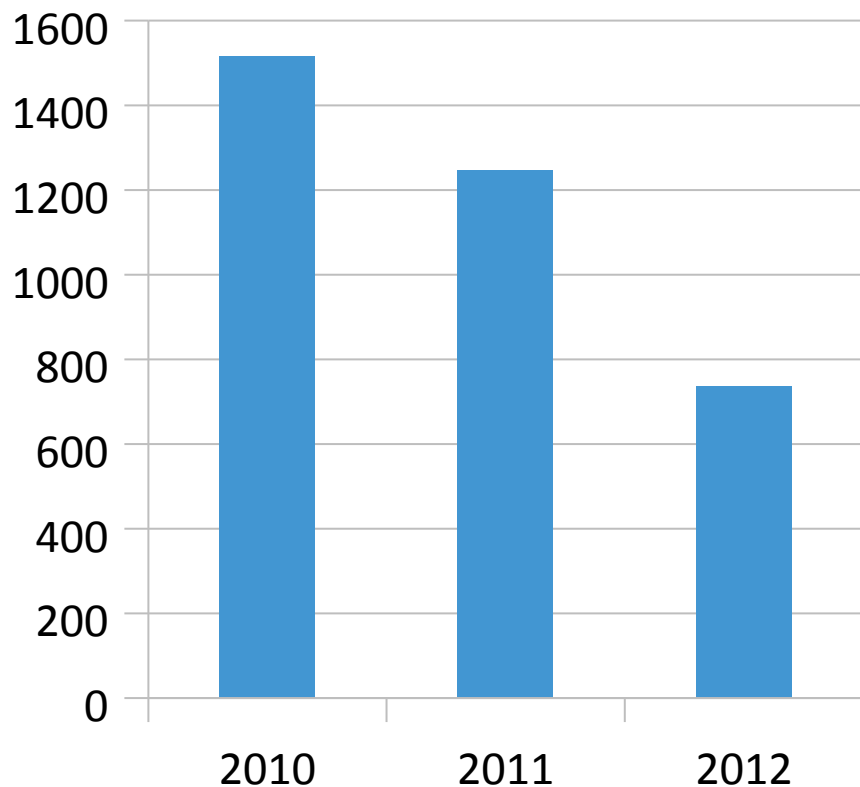
## Effective July 1, 2011

- ☐ Clinics must turn over their supply of C-II and C-III controlled substances
- ☐ Clinics are no longer able to dispense these drugs
- ☐ Clinics cannot have ANY affiliation with a doctor that has lost a DEA number

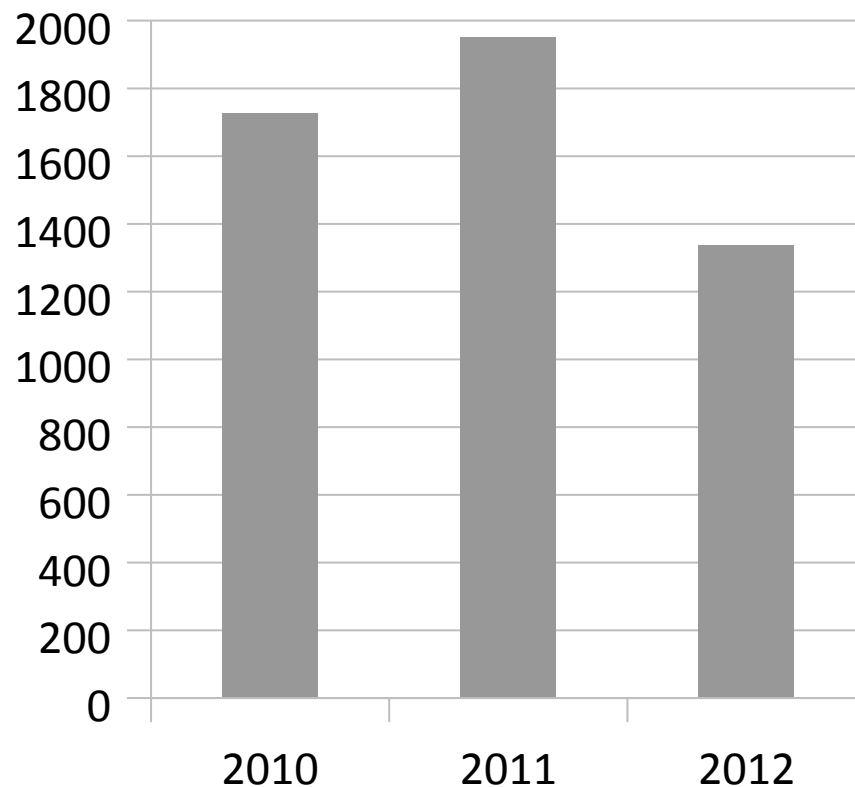
# Florida Medical Examiner's Office Data

## Positive Trends

### Oxycodone Related Deaths



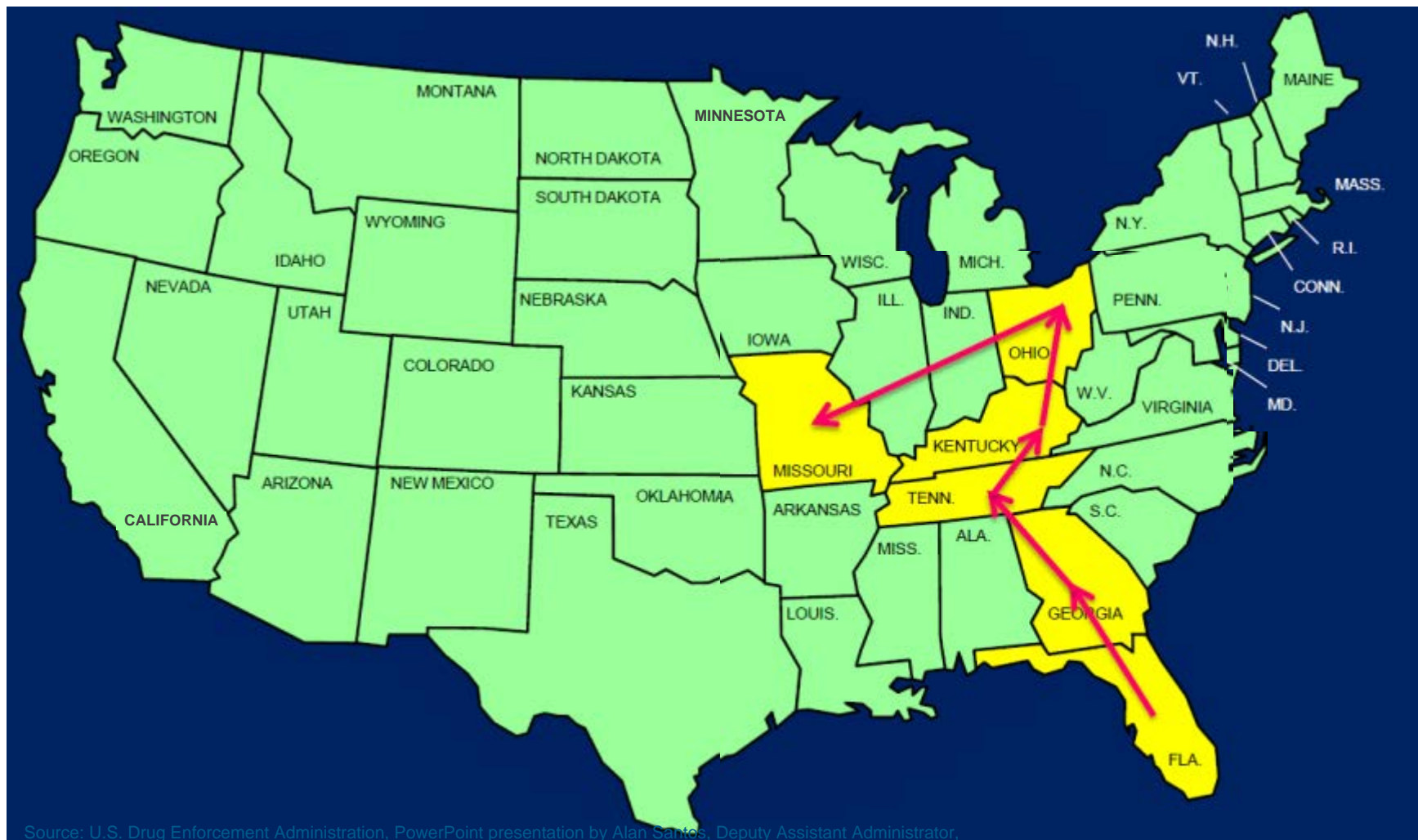
### Benzodiazepines Related Deaths



Source: Florida Medical Examiner's Office Annual Reports 2010, 2011, and 2012, <http://www.fdle.state.fl.us/Content/getdoc/0f1f79c0-d251-4904-97c0-2c6fd4cb3c9f/MEC-Publications-and-Forms.aspx>, accessed February 2014



# Drug Diversion Migration Out of Florida\*

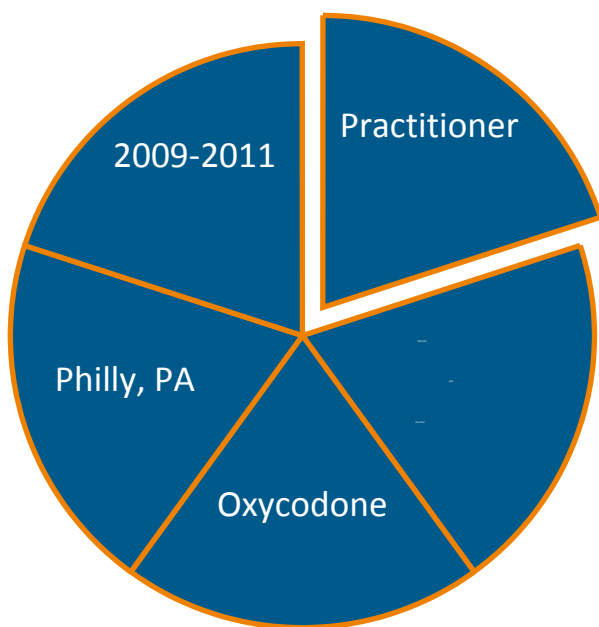


Source: U.S. Drug Enforcement Administration, PowerPoint presentation by Alan Santos, Deputy Assistant Administrator, Office of Diversion Control, Pharmacy Diversion Awareness Conference, Louisville, Kentucky, November 16-17, 2013, Prescription Drug Trafficking and Abuse Trends, [http://www.deadiversion.usdoj.gov/mtgs/pharm\\_awareness/conf\\_2013/nov\\_2013/santos.pdf](http://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/conf_2013/nov_2013/santos.pdf), accessed February 2014



# DEA Action: Practitioner

## Writing Illegal Prescriptions for Pseudo-patients



**DEA** UNITED STATES  
Drug Enforcement Administration  
TOUGH WORK, VITAL MISSION

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**PHILADELPHIA NEWS**

September 24, 2013  
Contact: Public Information Officer  
215-800-7761

**Doctor Sentenced for Running Pill Mill and Contributing to a Death**

**SEPT 24 (PHILADELPHIA)** – Dr. Norman Werther, 73, of Ft. Washington, PA, was sentenced today to 25 years in prison for distribution of a controlled substance resulting in death and more than 300 counts stemming from his pill mill operation. A federal jury convicted Werther on June 11, 2013 of 184 counts of illegally distributing oxycodone, 116 counts of money laundering, six counts of conspiracy to distribute controlled substances, and one count of maintaining drug-involved premises.

Werther was part of a multi-million dollar drug conspiracy involving illegal prescriptions, phony patients, and multiple drug trafficking organizations. At the time, Werther was a Montgomery County physician, running a physical therapy and rehabilitation practice in Willow Grove. He conspired with six separate groups of drug dealers. Werther was involved in the drug conspiracy between February 2009 and August 2011. The operation resulted in the illegal distribution of more than 700,000 pills containing oxycodone. At least one of the drug trafficking organizations working with Werther trafficked pills valued at more than \$5 million that Werther illegally prescribed.

"Instead of using his medical license to help people, Dr. Werther chose to generate tremendous profits by putting hundreds of thousands of pills on the street illegally," said First Assistant US Attorney Louis Lappen. "In one case, as the jury found, Dr. Werther's criminal enterprise and blatant disregard for the safety of the community caused the death of a patient whom Dr. Werther knew had a history of drug addiction. The court's sentence today will send a message to the community of consequences for those who engage in this type of activity."

**DEA Warns Public of Extortion Scams**

**Partnership Toolbox**  
National Prescription Take-Back Day

**The Dangers and Consequences of Marijuana Abuse**

**RESOURCE CENTER**

- Controlled Substances Act
- DEA Museum and Visitors Center
- Doing Business with DEA
- Drug Disposal
- Employee Assistance Program
- Extortion Scam Alert

# DEA Action: Hospital

## Prescriptions Issues Without Legitimate Medical Purpose

Hospital

Medical  
Residents

Adderall

New York

2008-2010

**DEA** UNITED STATES  
Drug Enforcement Administration  
TOUGH WORK. VITAL MISSION

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About » Office Locations » New York Division » New York Division News

### NEW YORK NEWS

September 20, 2013  
Contact: Public Information Officer  
Number: 212-337-2906

#### New York Methodist Hospital Agrees to Implement Compliance Program to Settle Civil Claims under the Controlled Substances Act

*Hospital's residents issued improper prescriptions for Adderall, a highly addictive stimulant*

**SEP 20 (BROOKLYN, N.Y.)** – Loretta E. Lynch, United States Attorney for the Eastern District of New York and Brian R. Crowell, Special Agent in Charge of the U.S. Drug Enforcement Administration, New York Division, announced today the filing and settlement of a civil action by the United States against New York Methodist Hospital ("NY Methodist"). Under a Consent Judgment, NY Methodist has agreed to implement measures designed to prevent the issuance of NY Methodist prescriptions in violation of the Controlled Substances Act and paid a civil penalty in the amount of \$70,000.

In the civil action, the United States alleges that between May 2008 and July 2010, medical residents employed by NY Methodist issued a total of 194 prescriptions for Adderall without a legitimate medical purpose. The medical residents employed by NY Methodist issued the prescriptions on prescription forms bearing the name of NY Methodist. The residents, acting with other individuals, then filled the prescriptions at local pharmacies. The residents themselves consumed some of the Adderall obtained by filling the prescriptions. The remainder of the Adderall was sold, either on Craigslist or in hand to hand transactions. In 2012, in a related criminal prosecution in this district, a former NY Methodist medical resident was convicted for conspiracy to distribute and possess with intent to distribute Adderall.

**DEA Warns Public of Extortion Scams**

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### RESOURCE CENTER

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- Doing Business with DEA
- Drug Disposal
- Employee Assistance Program
- Extortion Scam Alert
- For Victims of Crime

# DEA Action: Pharmacy/ Owner

## Filling Prescriptions Known to be Fraudulent

Pharmacy/  
Owner56,700 pills  
diverted in 45  
days

Oxycodone

Florida

2009-2012

**DEA** UNITED STATES  
Drug Enforcement Administration  
TOUGH WORK. VITAL MISSION.

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**MIAMI NEWS**

September 24, 2013  
Contact: Public Information Officer  
Number: 954-660-4602

**Pasco County Pharmacist Sentenced for Illegally Distributing Pain Medications**

**SEP 24 (TAMPA, Fla.)** – Mark R. Trouville, Special Agent in Charge (SAC), Drug Enforcement Administration (DEA), Miami Field Division, and A. Lee Bentley, III, Acting United States Attorney for the Middle District of Florida, announces that United States District Judge Susan Bucklew today sentenced Edward Benjamin Alistar Beckles (59, Pasco County) to four years in federal prison for distributing oxycodone. As part of his sentence, the court also entered a money judgment in the amount of \$175,000 from the criminal proceeds. Beckles was also ordered to serve a two-year term of supervised release. Beckles pleaded guilty on March 26, 2013.

In 2010, according to court documents the DEA and the Pasco County Sheriff's Office (PCSO) began an investigation to identify members of a large oxycodone distribution ring. As a result of the investigation, 33 individuals were arrested and prosecuted.

From August 2009 through January 2012, individuals obtained fraudulent prescriptions for oxycodone and had them filled at Ed's Family Friendly Pharmacy in New Port Richey. Beckles, a licensed pharmacist and owner of the pharmacy, filled the prescriptions knowing they were fraudulent. During the investigation, Beckles provided investigators with a computer printout that showed the pharmacy made in excess of \$130,000 in a 45-day period from the illegal sale of oxycodone. Approximately 210 fraudulent prescriptions, each for 270 pills, were filled in the 45-day period.

**RESOURCE CENTER**

- Controlled Substances Act
- DEA Museum and Visitors Center
- Doing Business with DEA
- Drug Disposal
- Employee Assistance Program
- Extortion Scam Alert
- For Victims of Crime
- How do I...?
- National Clandestine Laboratory Register
- Registration – for Practitioners
- Statistics & Facts
- Submit a Tip

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**Environmental Stewardship Policy**



# The Controlled Substances Act (CSA)

Congress carve out for controlled substances

Establishes a closed system of distribution

Creates checks and balances between registrants to protect the public health and safety

U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION  
OFFICE OF DIVERSION CONTROL

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RESOURCES > Title 21 USC Codified CSA > Section 801

**Title 21 United States Code (USC) Controlled Substances Act**

**SUBCHAPTER I — CONTROL AND ENFORCEMENT**

**Part A — Introductory Provisions**

**§801. Congressional findings and declarations: controlled substances**

The Congress makes the following findings and declarations:

- (1) Many of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.
- (2) The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.
- (3) A major portion of the traffic in controlled substances flows through interstate and foreign commerce. Incidents of the traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a substantial and direct effect upon interstate commerce because—
  - (A) after manufacture, many controlled substances are transported in interstate commerce,
  - (B) controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution, and
  - (C) controlled substances possessed commonly flow through interstate commerce immediately prior to such possession.
- (4) Local distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances.
- (5) Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate. Thus, it is not feasible to distinguish, in terms of controls, between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate.

[Cases Against Doctors](#)  
[Chemical Control Program](#)  
[CHSA \(Combat Meth Epidemic Act\)](#)  
[Controlled Substance Schedules](#)  
[DATA Waived Physicians](#)  
[Drug Disposal Information](#)  
[Drug and Chemical Information](#)  
[E-commerce Initiatives](#)  
[Federal Agencies & Related Links](#)  
[Federal Register Notices](#)  
[National TakeBack Initiative](#)  
[NFLIS](#)  
[Publications & Manuals](#)  
[Questions & Answers](#)  
[Significant Guidance Documents](#)  
[Title 21 Code of Federal Regulations](#)  
[Title 21 USC Codified CSA](#)

# Checks and Balances Under the CSA

## Practitioners

□ A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice. □

(21 CFR §1306.04(a))


The image shows two sample prescription forms. Both forms are for a patient named John Doe, MD, 123 Everywhere Street, City, ST 01234, TEL: (555)-555-0000, FAX: (555)-555-0000. The left form is for 'Zovirax 125mg' and the right form is for 'Amoxicillin 250mg/125mg'. Both forms include fields for patient name, address, age, date, and drug information. The left form has handwritten text: 'Zovirax 125mg', '# 30', 'Sig. 2x6: 11:00'. The right form has handwritten text: 'Amoxicillin 250mg/125mg', '3/4 tsp tid p.o.', '100g'. Both forms have a blue footer with the text: 'DRUG: ?', 'QUANTITY: ?', 'DAY SUPPLY: ?', 'DIRECTIONS: ?'.

# Checks and Balances Under the CSA

## Pharmacists

A pharmacist, by law, has a Corresponding Responsibility to ensure that prescriptions are legitimate.

☐ The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. ☐ (21 CFR § 1306.04(a))



Just because a prescription is presented by a patient or demanded to be filled for a patient by a doctor's office, pharmacists are **not** obligated to fill the prescription!

# Checks and Balances Under the CSA

## Distributors



Wholesaler Distributors

☐ Maintenance of ***effective controls against diversion*** of controlled substances into other than legitimate medical, scientific, and industrial channels; ☐ (21 U.S.C. § 823.)

☐ The registrant shall design and operate a system to disclose to the registrant ***suspicious orders of controlled substances***. Suspicious orders include orders of unusual ***size***, orders deviating substantially from a normal ***pattern***, and orders of unusual ***frequency***. ☐ (21 CFR §1301.74(b))

# DEA Perspective

## Indicators of Prescription Drug Diversion

- Increase in volume
- Significant growth of abused drugs
- Non-numerical red flags

## Understand the Numbers

- Geographical and regional statistics and norms
- Average pharmacy orders 73,000 Oxycodone doses per year\*

## Meet Regulatory Obligations

- Effective controls against diversion
- Suspicious order monitoring
- Corresponding responsibility

\* J. Arnold, Drug Enforcement Administration, Office of Diversion Control: Effective Controls Against Diversion presentation 2013



# Potential Red Flags

## Patients that ☐

- ☐ Receive the *same combination* of prescriptions
- ☐ Receive the *same strength* of controlled substances
- ☐ *Pay in cash* for their prescriptions
- ☐ Have the *same diagnosis codes* written on their prescriptions
- ☐ *Drive long distances* to visit physicians and/or to fill prescriptions
- ☐ Enter the pharmacy in *groups*, each with the *same prescriptions* issued by the *same physician*
- ☐ Have prescriptions for controlled substances *written by physicians not associated with pain management* (i.e. pediatricians, gynecologists, ophthalmologists, etc).

- Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control: Drug Enforcement Administration. June 30, 2012

# Wholesale Distributors Responsibility



Wholesaler Distributors

## Individually and collectively:

- ☐ Our DEA registration
- ☐ Ensure timely distribution to prevent an uninterrupted supply; and
- ☐ Distributors control the supply to downstream customers